

**Notice of Allowability**

Application No.

10/735,153

Examiner

Melanie Yu

Applicant(s)

BALLERSTADT ET AL.

Art Unit

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's amendment filed 10 April 2006.
2. ☒ The allowed claim(s) is/are 1-31, 71-80 and 102-123 (renumbered claims 1-63, respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The Title has been changed to: --Assay and Method for Analyte Sensing by Detecting Efficiency of Radiation Conversion--.

### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance: the prior art fails to teach a macroporous matrix with a plurality of beads or particles embedded in the matrix wherein a radiation converting component having a conversion efficiency that is independent of the concentration of analyte is embedded in or attached to at least one of the plurality of beads.

Krauth et al. (US 4,954,435) teach a reporter fluorophore (first radiation converting component, conversion efficiency dependent on analyte concentration) and a reference fluorophore (second radiation component, conversion efficiency independent of analyte concentration) in a housing and a ligand for specifically binding analyte, but fail to teach the reference fluorophore attached to or embedded in at least one of a plurality of beads and a macroporous matrix.

Polak et al. (US 2002/0182658) teach a housing comprising a porous matrix, wherein a first radiation converting component having a conversion efficiency dependent on the concentration of analyte and a second radiation converting component (reference component) having a conversion efficiency independent of the analyte concentration are both contained within the porous matrix and an analyte-specific binding ligand attached to

Art Unit: 1641

the porous matrix. However, Polak et al. fail to teach the second radiation converting component embedded or attached to a plurality of beads or particles.

Dickinson et al. (US 6,942,968) teach a porous particle having an embedded first radiation converting component (radiation converting efficiency dependent on analyte concentration) and an embedded second radiation converting component (radiation converting efficiency independent of analyte concentration), but fail to teach the bead embedded in a porous matrix. Dickinson et al. also fail to teach motivation to further embed the porous particle in the porous matrix of Polak et al. because the porous bead of Polak et al. is placed in a well for analysis.

Buschmann et al. (US 2003/0147862) teach a first radiation converting component (conversion efficiency dependent on analyte concentration) and a second radiation converting component (conversion efficiency independent of analyte concentration) each embedded in separate microspheres for flow cytometry analysis. However, because Buschmann et al. use flow cytometry for analysis, the reference fails to provide no motivation for putting the microspheres in the porous matrix of Polak et al.

Walt et al. (US 2003/0027126) and Chee et al. (US 6,544,732) teach microspheres with embedded dyes and attached ligands for binding to analyte and identification purposes and placed in a porous material, but fail to teach motivation to embed a second radiation converting component in a microsphere wherein the analyte-specific binding ligand is attached to a porous matrix and not the microsphere.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1641


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1641



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